REMARKS

Claims 1-6, 16-18 and 21-22 were rejected under 35 U.S.C.§103(a) as being unpatentable over Oshlack et al. (Oshlack) in view of Meissner.

Reconsideration is requested.

Claim 1 points out a "solid pharmaceutical dosage form which comprises an opiate, an opiate antagonist and an amount of hydrocolloids and other excipients including starch, lactose, xanthan gum, locust bean gum, monobasic calcium phosphate, dibasic calcium phosphate, microcrystalline cellulose, propylene glycol alginate, zein and magnesium stearate which are effective to form a viscous, non-injectable matrix when said dosage form is contacted with water.

This formulation is not made obvious by Oshlack who mentions many formulations but none having the components of claim 1 or components which result in a non-injectable formulation when one attempts to add water for the purpose of making the opioid oral dosage form injectable. The advantage of prevent intravenous drug abusers from using solid dosages o opioid drugs is readily apparent and it is not taught by the Oshlack patent. It is not seen how a reference can make obvious a formulation having ingredients that are not disclosed by the reference. Since Oshlack does not mention the ingredients of claim 1, the composition of claim 1 cannot be made based on the teachings of Oshlack.

Claims 6 and 22 recite a formulation or method where the pellets are enteric coated pellets. This formulation is not made obvious by Oshlack and or Meissner who do not disclose an enteric coated formulation. Claim 16 points out

a specific three pellet formulation where the pellets are formulated to release the drugs in specific anatomical locations of the small intestine. This formulation is also not made obvious by Oshlack. Claim 22 points out a method of treating constipation caused by opiates where the opiate antagonist is administered in the form of enteric coated pellets. Nothing in Oshlack or Meissner makes claim 22 obvious.

Claim 18 is directed to a method of preventing the formulation of an parenteral formulation of a solid oral dosage form of an opiate by adding a hydrocolloid-excipient combination to a solid oral dosage formulation of an opiate so that when said solid oral dosage form contacts water, a matrix is formed which is too viscous to be injected via a hypodermic needle. This is not suggested in any way by the teachings of Oshlack and Meissner. The Meissner reference points out that each patient must be titrated with the amount of naloxone antagonist to determine the dose for treating or preventing constipation. This makes each patient a research project and does not provide information as to how to make a dosage form. The claims of the present application point out that microcrystalline cellulose, propylene glycol alginate, zein and magnesium stearate are used to form a viscous, non-injectable matrix, when the dosage form is contacted with water. This formulation releases the naloxone at the end of the small intestine and in the large intestine and thus preventing constipation without the need to adjust or titrate the dose to experimentally determine what dose will prevent constipation.

The cited references do not make obvious the claimed composition and for these reasons, the rejection should be withdrawn.

An early and favorable action is earnestly solicited.

Respectfully submitted,

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